



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2017-F-0969]

Food Additives Permitted in Feed and Drinking Water of Animals; Spent Bleaching Clay

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; petition for rulemaking; amendment.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending a notice of petition announcing that the Canadian Oilseed Processors Association has filed a petition proposing that the food additive regulations be amended to provide for the safe use of spent bleaching clay as a flow agent in canola meal for all livestock and poultry species.

Additionally, the petition proposes that the regulations be amended to provide for the safe use of silicon dioxide and diatomaceous earth for use as components of spent bleaching clay. This petition included a request for categorical exclusion, but after review we determined the petitioner should prepare an environmental assessment (EA). The petitioner has prepared and submitted an EA, which at this time is being placed in the docket for public review and comment.

DATES: Submit either electronic or written comments on the petitioner's environmental assessment by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before

[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-F-0969 for "Food Additives Permitted in Feed and Drinking Water of Animals; Spent Bleaching Clay." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the

body of your comments and you must identify this information as "confidential."

Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Chelsea Trull, Center for Veterinary Medicine, Food and Drug Administration, (HFV-224), 7519 Standish Pl., Rockville, MD 20855, 240-402-6729, chelsea.trull@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)(5)), notice was given in the *Federal Register* of April 18, 2017 (82 FR 18268), that a food additive petition (FAP 2299) has been filed by the Canadian Oilseed Processors Association, 404-167 Lombard Ave., Winnipeg MB R3B 0T6, Canada. The petition proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 *Food Additives Permitted in Feed and Drinking Water of Animals* (21 CFR part 573) to provide for the safe use of spent bleaching clay as a flow agent in canola meal for all livestock and poultry species.

Additionally, the submission proposes that the existing regulations be amended to provide for the

safe use of silicon dioxide (21 CFR 573.940) and diatomaceous earth (21 CFR 573.340) for use as components of spent bleaching clay.

This petition included a request for categorical exclusion, but after review we determined the proposed action on spent bleaching clay does not meet the criteria for a categorical exclusion under 21 CFR 25.32(r). The petitioner has prepared and submitted an EA.

We are reviewing the potential environmental impact of this petition. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), we are placing the EA submitted with the petition that is the subject of this notice on public display at the Dockets Management Staff (see DATES and ADDRESSES) for public review and comment.

We will also place on public display, at the Dockets Management Staff and at <https://www.regulations.gov>, any amendments to, or comments on, the petitioner's EA without further announcement in the *Federal Register*. If, based on our review, we find that an environmental impact statement is not required, and this petition results in a regulation, we will publish the notice of availability of our finding of no significant impact and the evidence supporting that finding with the regulation in the *Federal Register* in accordance with 21 CFR 25.51(b).

Dated: March 13, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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